(12) UK Patent Application (19) GB (11) 2 366 733 (13) A

(43) Date of A Publication 20.03.2002

(21) Application No 0110080.9

(22) Date of Filing 24.04.2001

(71) Applicant(s)
Corin Limited
(Incorporated in the United Kingdom)
The Corinium Centre, Cirencester, Gloucestershire, GL7 1YJ, United Kingdom

(72) Inventor(s)
Peter Jeremy Gibson

(74) Agent and/or Address for Service
A R Davies & Co
27 Imperial Square, CHELTENHAM, Gloucestershire, GL50 1RQ, United Kingdom

(51) INT CL[7]
A61F 2/32

(52) UK CL (Edition T)
A5R RABA

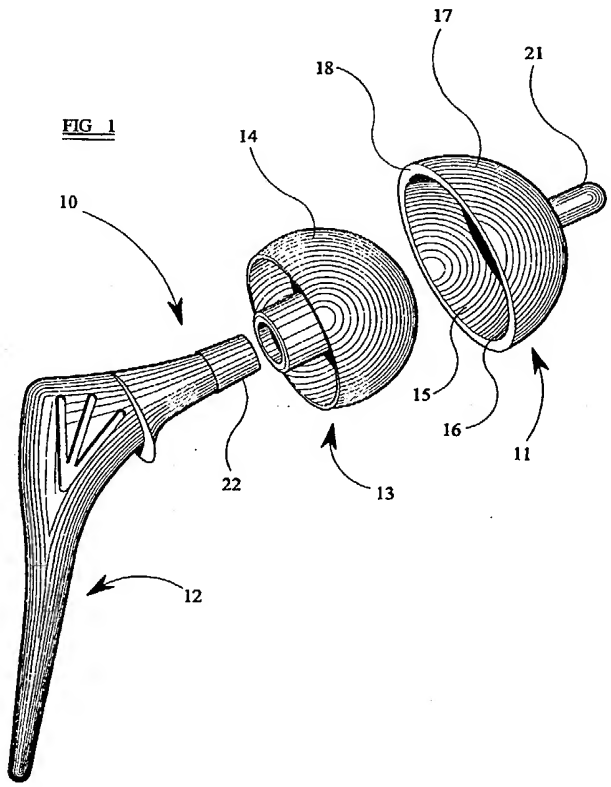
(56) Documents Cited
GB 2315222 A
US 6126695 A
US 5879406 A
GB 2159416 A
US 6120545 A

(58) Field of Search
UK CL (Edition S) A5R RABA RABX RAG
INT CL[7] A61F 2/32 2/34 2/36
Online: EPODOC, WPI, JAPIO

(54) Abstract Title
A hip prosthesis

(57) A total hip replacement prosthesis is disclosed. This prosthesis comprises a femoral component 10 and an acetabular cup 11. The femoral component 10 has a femoral stem 12 and a head 13 defining a first part spherical articulating surface. The cup 11 has a recess 16 defining a second part spherical articulating surface. The articulating surfaces of the head and the cup are formed of metal, a ceramic material or other hard bearing biocompatible material. The head has a diameter of at least 35 mm and the radius of the head is between 25 and 300 μm less than the radius of the recess in the cup.

FIG 1



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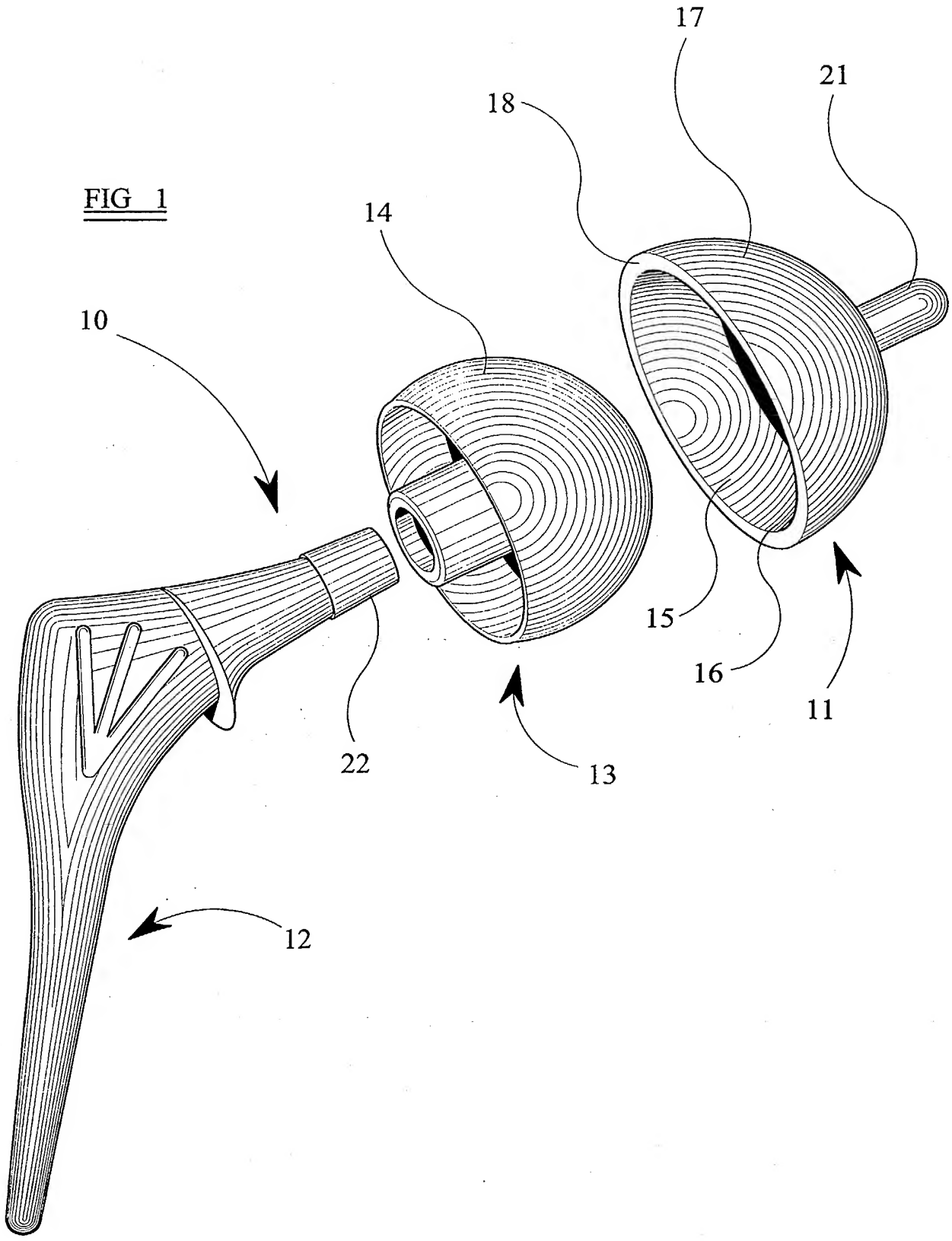
At least one drawing originally filed was informal and the print reproduced here is taken from a later filed formal copy.

FIG 1



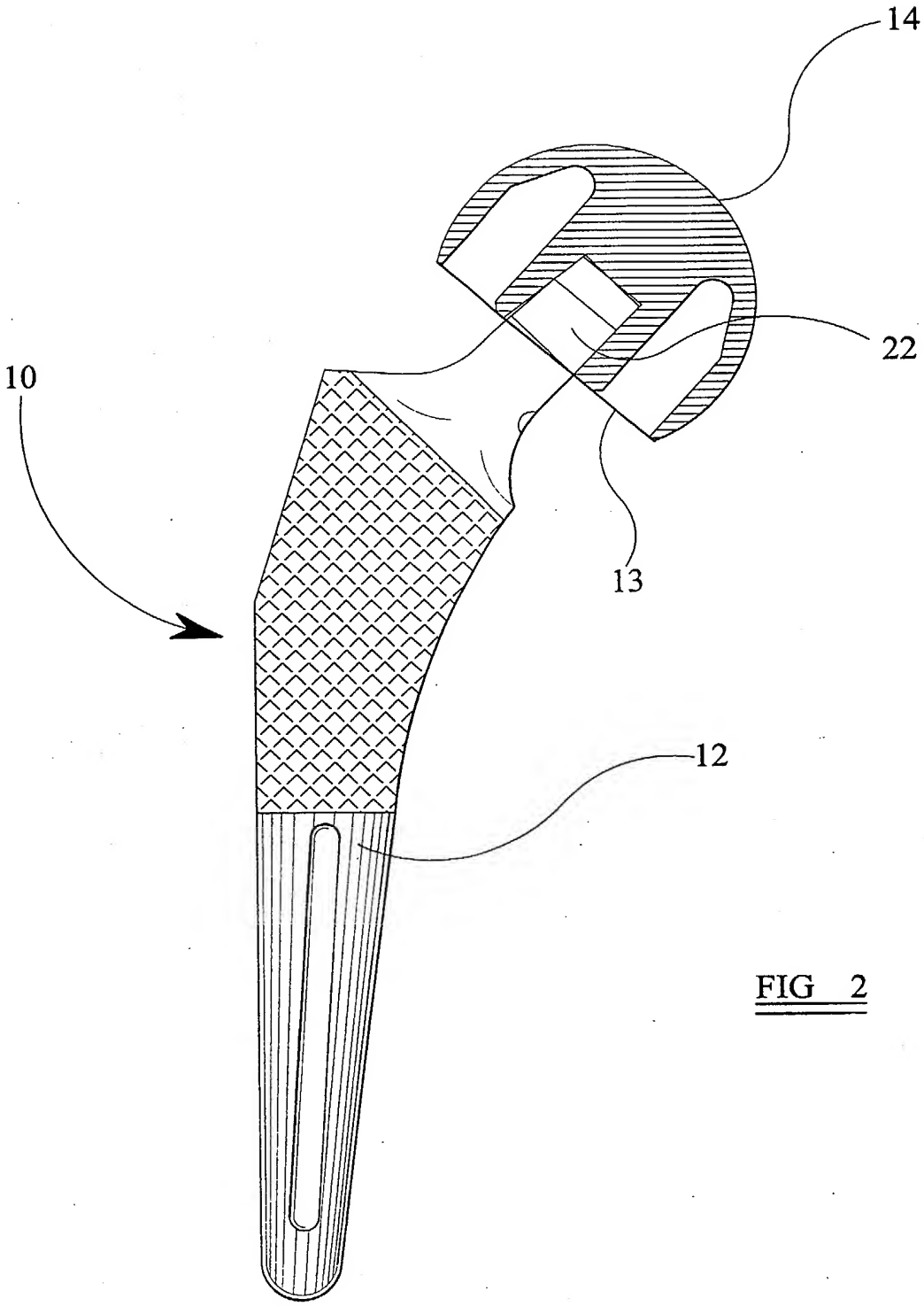


FIG 2

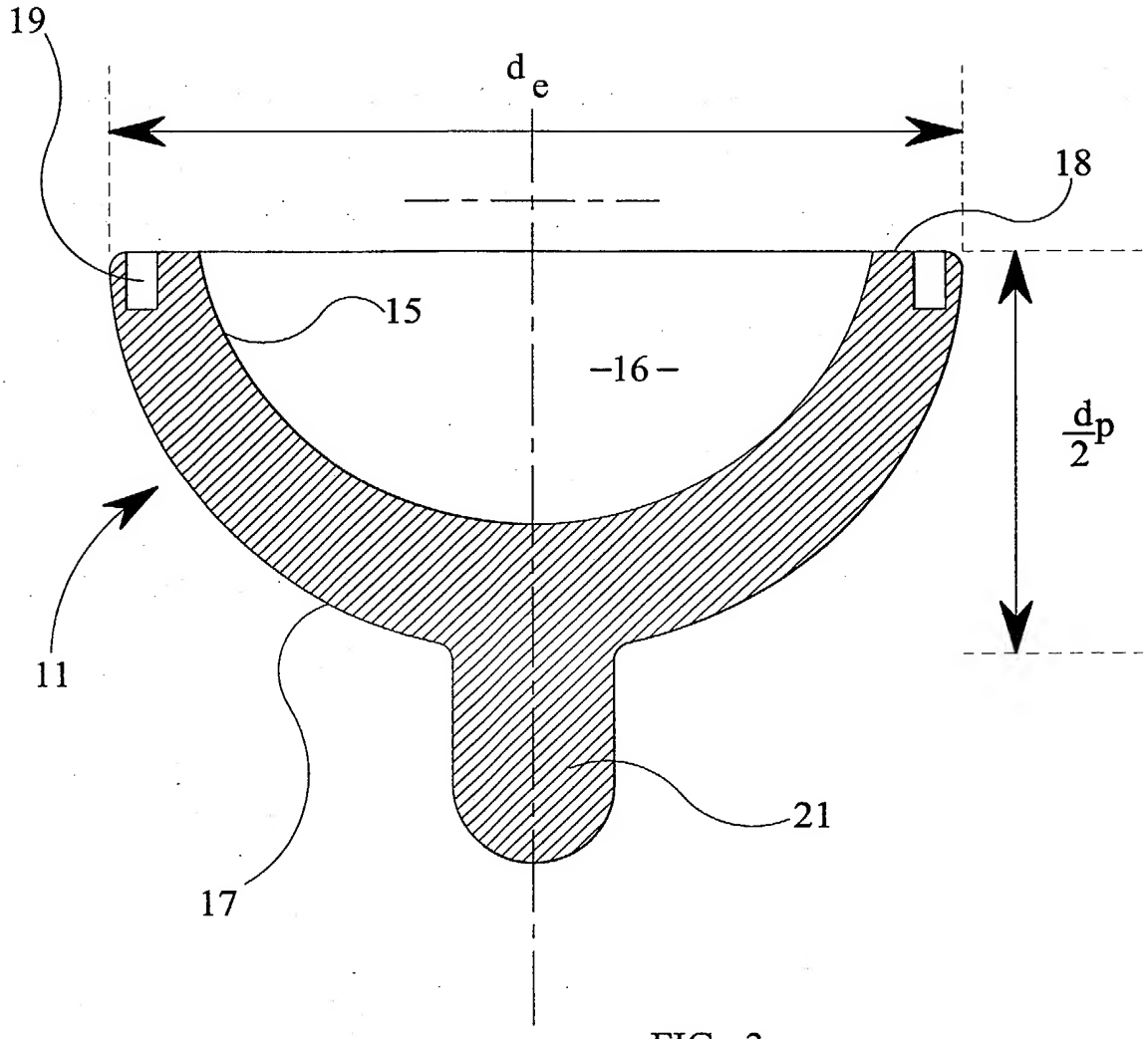


FIG 3

A HIP PROSTHESIS

This invention relates to a hip prosthesis and more particularly to a total hip replacement prosthesis.

Treatment of degenerative arthritis of the hip by conventional total hip replacement has, in the main, been highly successful, with typical survivorship achieving 90% at 10 years. There are, however, a number of clinical complications that can arise. These include: early dislocation (typically 3 - 4%), mechanical loosening and osteolysis resulting from polyethylene wear debris. The deleterious effect of polyethylene debris became increasingly understood throughout the 1990s and, as a consequence, there has been a re-emergence of interest in metal on metal bearing prostheses, thus avoiding the use of polyethylene.

Currently, there are two types of metal on metal total hip replacement prosthesis available in clinical use. These are: small diameter (22-32 mm) stemmed total hip replacement and large diameter (35 mm +) surface replacement prostheses. Both types are manufactured from high carbon cobalt chrome and require high levels of sphericity and surface finish.

A large diameter metal on metal prosthesis would appear to have a number of advantages over a small diameter metal on metal prosthesis. These advantages

include: resistance to dislocation (i.e. more stable), more anatomical (i.e. providing better bone loading and, therefore, bone integrity) and, most importantly, an enhanced ability to achieve a natural lubrication regime through entrainment of pseudo synovial fluid between the two metal articulating surfaces. As a consequence of this enhanced lubrication, large diameter metal on metal prostheses theoretically exhibit lower wear rates than small diameter metal on metal prostheses.

However, large diameter metal on metal surface replacement prostheses are only suitable for the younger patient, where the femoral neck is sufficiently strong to resist fracture. 90% of all people over 60 suffer from osteo-arthritis and 200 million people worldwide are affected by osteo-porosis. As a consequence, surface replacement may be contra indicated in the elderly patient, who would be at risk of femoral neck fracture following, and exacerbated by, implantation of a surface replacement prosthesis.

According to the present invention there is provided a total hip replacement prosthesis comprising a femoral component and an acetabular cup, the femoral component having a femoral stem and a head defining a first part spherical articulating surface and the cup having a recess defining a second part spherical articulating surface, wherein the articulating surfaces of the head and the cup are formed of metal, a ceramic material or other hard bearing biocompatible material, the head has a diameter of at least 35 mm and the radius of the head is between 25 and

300 μm less than the radius of the recess in the cup.

It is thus possible to provide a prosthesis having a number of advantages over conventional total hip replacement prostheses. These advantages may include:

a. A self-lubricating regime between the head and the cup thereby minimising wear.

b. The absence of polyethylene and, therefore, polyethylene debris.

c. A reduced risk of post-operative dislocation owing to the use of a relatively large head.

d. Improved anatomical bone loading as a result of essentially retaining the anatomical dimensions of the femoral head and cup.

Preferred and/or optional features are set forth in claims 2 to 12.

The invention will now be more particularly described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is an exploded perspective view of one embodiment of a total hip replacement prosthesis according to the present invention,

Figure 2 is a side view, partly in section, of the femoral component of the hip

prosthesis shown in Figure 1, and

Figure 3 is a sectional view through the acetabular cup of the hip prosthesis shown in Figure 1.

Referring to the drawings, the total hip replacement prosthesis shown therein comprises a femoral component 10 and an acetabular cup 11. The femoral component 10 comprises a femoral stem 12, which is shaped to fit within the femoral cavity of the femur, and a head 13 defining a first part spherical articulating surface 14.

The acetabular cup 11 has a recess 16. The recess 16 defines a second part spherical articulating surface 15 which is preferably hemi-spherical or substantially hemi-spherical. The cup 11 also has an outer surface 17 of an appropriate diameter to fit into the acetabulum of a patient.

The femoral component 10 and cup 11 could be implanted using bone cement. Alternatively, one or both could be implanted using a porous in-growth coating for direct fixation to the host bone.

Extending between the outer surface 17 and the articulating surface 15 is an annular rim 18. The surface of the rim 18 is planar. The rim 18 is provided with at least one and preferably three equi-angularly spaced introducer recesses 19 (shown

in Figure 3). The recesses 19 open out only into the rim 18 and are spaced from the outer surface 17 and the inner surface 15. The recesses 19 are provided to receive an introducer tool (as described in GB-A-2333961) for introducing and locating the cup 11 in the acetabulum of a patient.

To improve the fixation of the acetabular cup 11 in the acetabulum of the patient, the outer surface of the cup may be textured and/or comprise a plurality of splines (not shown). A supra-medial peg 21 may also extend from the outer surface 17 of the cup. As mentioned above, the acetabular cup could be implanted using a porous in-growth coating for direct fixation to the host bone. To ensure that the cup 11 remains within the acetabulum before it becomes fixed by boney in-growth, the cup is shaped such that the equatorial diameter d_e of the outer surface 17 is greater than the polar diameter d_p of the outer surface 17. The acetabulum is reamed to the same dimension as the polar diameter d_p and the cup 11 can then be jammed into the acetabulum due to the larger equatorial diameter of the cup.

The cup 11 and the head 13 of the femoral component 10 are preferably both formed of metal and more preferably of high carbon cobalt chrome. One or both of the cup 11 and head 13 could, however, be formed of a suitable biocompatible material and provided with a metal liner to define the articulating surface(s). Alternatively, the cup 11 and/or head 13 could be formed of, or lined with, a ceramic material, such as zirconia, or other hard bearing biocompatible material, such as

glass, diamond or a diamond like material.

The head 13 is what is commonly referred to in the art as a large diameter head having a diameter of at least 35 mm, and typically having a diameter of between 40 and 56 mm. A large diameter head reduces the risk of post-operative dislocation and improves anatomical bone loading. The radius of the head is between 25 and 300 μm less than the radius of the recess 16 in the cup 11 and optimally between 100 and 200 μm less than the radius of the recess 16. This radial mismatch between the cup 11 and the head 13 is deliberately machined into the cup and the head to enhance the ability of the prosthesis to achieve a natural lubrication regime through entrainment of pseudo synovial fluid between the articulating surfaces and as a consequence of this enhanced lubrication the wear rate of the prosthesis is reduced. Also, the head 13 will bear on the pole of the cup 11.

The sphericity of the head (as defined by ISO 7206-2 1996 Section 4.1.1) is less than 10 μm.

The femoral stem 10 is typically formed of titanium alloy, or cobalt chromium alloy or stainless steel. The head 13 is attached to the femoral stem 10 by a tapered trunnion 22 of the type commonly referred to in the art as a Morse Taper. Alternatively, the head 13 could be an integral part of the stem 10.

The surface finish of the articulating surfaces of the head 13 and the recess 16 is less than 0.05 μm.

A range of head and cup diameters could be made available to match the size of the patient. In this case, the internal diameters of the cups and the diameters of the heads will vary according to the external dimensions of the cups which will match the size of the patient's acetabulum.

The embodiments described above are given by way of example only and various modifications will be apparent to persons skilled in the art without departing from the scope of the invention as defined by the appending claims.

CLAIMS

1. A total hip replacement prosthesis comprising a femoral component and an acetabular cup, the femoral component having a femoral stem and a head defining a first part spherical articulating surface and the cup having a recess defining a second part spherical articulating surface, wherein the articulating surfaces of the head and the cup are formed of metal, a ceramic material or other hard bearing biocompatible material, the head has a diameter of at least 35 mm and the radius of the head is between 25 and 300 μm less than the radius of the recess in the cup.

2. A hip prosthesis as claimed in claim 1, wherein the radius of the head is between 100 and 200 μm less than the radius of the recess in the cup.

3. A hip prosthesis as claimed in claim 1 or claim 2, wherein the sphericity of the head is less than 10μm.

4. A hip prosthesis as claimed in any one of the preceding claims, wherein the surface finish of the articulating surfaces of the head and the recess in the cup is less than 0.05 μm.

5. A hip prosthesis as claimed in any one of the preceding claims, wherein the articulating surfaces of the head and the cup are formed of metal.

6. A hip prosthesis as claimed in claim 5, wherein the metal is high carbon cobalt chromium alloy.

7. A hip prosthesis as claimed in any one of claims 1 to 4, wherein the articulating surfaces of the head and the cup are formed of a ceramic material.

8. A hip prosthesis as claimed in any one of the preceding claims, wherein the equatorial diameter of the outer surface of the cup is greater than the polar diameter thereof.

9. A hip prosthesis as claimed in any one of the preceding claims, wherein the cup has an annular rim between its outer surface and its articulating surface and wherein the rim has at least one recess engageable by an introducing device for enabling introduction and location of the cup in a patient's acetabulum.

10. A hip prosthesis as claimed in any one of the preceding claims, wherein the head is adapted to bear on the pole of the cup.

11. A hip prosthesis as claimed in any one of the preceding claims, wherein the head is permanently attached to the femoral stem.

12. A hip prosthesis as claimed in any one of claims 1 to 10, wherein the head is

attached to the femoral stem by a tapered trunnion.

13. A hip prosthesis substantially as hereinbefore described with reference to the accompanying drawings.

Amended claims have been filed as follows

CLAIMS

1. A total hip replacement prosthesis comprising a femoral component and an acetabular cup, the femoral component having a femoral stem and a head defining a first part spherical articulating surface and the cup having a recess defining a second part spherical articulating surface, wherein the articulating surfaces of the head and the cup are formed of metal and wherein the head has a diameter of at least 35 mm and a radius which is between 25 and 300 μm less than the radius of the recess in the cup.

2. A hip prosthesis as claimed in claim 1, wherein the radius of the head is between 100 and 200 μm less than the radius of the recess in the cup.

3. A hip prosthesis as claimed in claim 1 or claim 2, wherein the sphericity of the head is less than 10μm.

4. A hip prosthesis as claimed in any one of the preceding claims, wherein the surface finish of the articulating surfaces of the head and the recess in the cup is less than 0.05 μm.

5. A hip prosthesis as claimed in any one of the preceding claims, wherein the metal is high carbon cobalt chromium alloy.

6. A hip prosthesis as claimed in any one of the preceding claims, wherein the equatorial diameter of the outer surface of the cup is greater than the polar diameter thereof.

7. A hip prosthesis as claimed in any one of the preceding claims, wherein the cup has an annular rim between its outer surface and its articulating surface and wherein the rim has at least one recess engageable by an introducing device for enabling introduction and location of the cup in a patient's acetabulum.

8. A hip prosthesis as claimed in any one of the preceding claims, wherein the head is adapted to bear on the pole of the cup.

9. A hip prosthesis as claimed in any one of the preceding claims, wherein the head is permanently attached to the femoral stem.

10. A hip prosthesis as claimed in any one of claims 1 to 8, wherein the head is attached to the femoral stem by a tapered trunnion.

11. A hip prosthesis substantially as hereinbefore described with reference to the accompanying drawings.

INVESTOR IN PEOPLE

Application No: GB 0110080.9 13 **Examiner:** Lee Ellison
Claims searched: 1-13 **Date of search:** 15 November 2001

Patents Act 1977
Search Report under Section 17

Databases searched:

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.S): A5R (RABA, RABX, RAG)

Int Cl (Ed.7): A61F 2/32, 2/34, 2/36

Other: Online: EPODOC, WPI, JAPIO

Documents considered to be relevant:

Category	Identity of document and relevant passage		Relevant to claims
A	GB2315222A	(HARDINGE) See figure 1-3; page 3 line 21 - page 4 line 4; page 6 lines 3-24.	
A	GB2159416A	(TRONZO) See figures 1 & 4; page 1 lines 4-9; & page 3 lines 52-61.	
X, Y	US6126695A	(SULZER ORTHOPAEDIE AG) See figures 1, 2a & 2b reference numerals A, B, R, r & 1; column 1 lines 5-12 & 32-45; column 2 lines 4-5; & column 4 lines 45-47.	X = 1, 4, 5, 12 Y = 1, 4, 5, 7, 12
X, Y	US6120545A	(ACCIS BV, VAN DOORN, VAN STRATEN) See figures 1, 3a & 3b reference numerals 1-4, 9, 10, 10' & d; column 1 lines 4-6 & 49-60; column 2 lines 5-10, 16-23 & 37-44; & claim 1 parts 1 & 2.	X = 1, 2, 7 Y = 1, 4, 5, 7
Y	US5879406A	(SAINT-GOBAIN INDUSTRIAL CERAMICS INC.) See figures 2a & 11 reference numerals 20, 52, 55, 63 & 65; column 3 lines 62-64; column 7 lines 48-52; column 7 lines 54-57 & 59-64; & column 8 line 56 - column 9 line 15.	1, 4, 5, 7, 12

X	Document indicating lack of novelty or inventive step	A	Document indicating technological background and/or state of the art.
Y	Document indicating lack of inventive step if combined with one or more other documents of same category.	P	Document published on or after the declared priority date but before the filing date of this invention.
&	Member of the same patent family	E	Patent document published on or after, but with priority date earlier than, the filing date of this application.